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10/517,776	07/19/2005	Jacques Bellalou	263894US2PCT	1227
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HOBBS, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/517,776	Applicant(s) BELLALOU ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 01/05/2009 has been considered and entered for the record. Applicant's amendment overcomes the objection to the claims in paragraph 3 of the Office Action mailed on 08/04/2008. Claims 1-6 and 9-15 are pending further examination upon the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 2002/0155619 A1) in view of Gaillon et al (WO 99/27349) (with US 6,723,554 B1 being the closest English language translation).

6. Kurihara discloses an apparatus for detecting fluorescence in a liquid sample that for claim 1 includes a motor (motor 7) that rotates a partition plate (plate 3) which supports a LED light source (source 8) and an optical unit (unit 6) that receives the light emitted from a sample container ([0047]; [0053]) where the container is fully capable of holding a cell culture. Furthermore, the partition plate is being interpreted as the "mobile sensor holder" the optical unit (unit 6) is being interpreted as the external sensor. Also, light from the container is sent from the optical unit to an optical sensor (sensor 2) that measures and monitors the sample "in real time" ([0050]). The temperature of the sample is controlled by a thermostatic unit that includes a temperature sensor (sensor 9a) and a heater (heater 9b) where this system is a Peltier element ([0056]; [0058]). However, Kurihara is silent regarding a sample container with a useful volume between 2 to 500 ml.

7. Gaillon discloses a method for measuring the optical properties of a sample by feedback control. For claim 1, Gaillon discloses a container that has a useful volume between 10 ml and 60 ml which is used as a fermentor (col. 13 lines 2-4; col. 18 lines

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16-19). Furthermore, adjusting the volume of the base device of Kurihara with the volume of Gaillon would be within the skills of one of ordinary skill in the art based on throughput requirements for testing or the amount of sample to be fermented.

Therefore, it would have been obvious to one of ordinary skill in the art to employ the fermentor with the volume suggested by Gaillon within the device of Kurihara in order to obtain the predictable result of fermenting and testing a sample.

8. With regards to claim 3, Kurihara does not disclose a second sensor, however, the use of a second sensor would allow measurements to be taken from more than one region of the sample container and would allow the sensor to account for the dispersion/settling of the sample. Therefore, it would be obvious to one of ordinary skill in the art to employ a second sensor within Kurihara in order to obtain more readings from the sample container. See MPEP 2144.04 VI (B).

9. With regards to claim 4, the sensor monitors the fluorescence of the sample as discussed above. For claim 5, as detailed in Figure 2, Kurihara discloses a partition platform or mobile carriage that is connected to a motor or driving system that allows for circular movement of the optical unit. and since the optical unit is connected to the partition platform which in turn is connected to the motor, this strongly implies that the motion of the optical unit is circular.

10. Regarding claims 11-15, the limitations of these claims do not provide any structural limitations that distinguishes the claimed invention over the prior art and therefore, Kurihara is fully capable of being able to "optimize cell culture methods", "make the analysis of gene expression mechanisms" where "the genes are involved in

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cell adherence mechanisms” and the device is fully capable of being able to study physical and physiochemical mechanisms”.

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 2002/0155619 A1) in view of Gaillon et al (WO 99/27349) (with US 6,723,554 B1 being the closest English language translation) and in further view of Bannerjee (US 6,307,630 B1).

12. Kurihara discloses an LED for sending light to the sample, but is silent regarding a receiving diode. Gaillon discloses that the emitted light is received by a photo-darlington type photo-detector (col. 11 lines 49-50), but does not mention a receiving diode.

13. Bannerjee discloses a turbidimeter array system that uses a common light source and detector to obtain optical data from a plurality of test samples. For claim 2, Bannerjee discloses that the turbidity sensor includes a light source which is a light emitting diode and a detector which is a photodiode (col. 3 lines 58-64). Other solutions to receiving light from the sample also include a photomultiplier tube, an avalanche photodiode, a CCD, a mirror or optical fiber. Furthermore, Bannerjee demonstrates that a receiving diode was a known element at the time of the instant application. Therefore, it would have been obvious to one of ordinary skill in the art to employ the photodiode as suggested by Bannerjee within the optical unit of Kurihara and Gaillon in order to obtain the predictable result of sending the light from the sample container to a sensor.

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14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 2002/0155619 A1) in view of Gaillon et al (WO 99/27349) (with US 6,723,554 B1 being the closest English language translation) and in further view of Bell et al. (US 5,814,277).

15. Kurihara does not disclose a sampling or injecting system independent of the mobile sensor.

16. Bell discloses an automatic multiple-sample, multiple-reagent chemical analyzer that includes a rotary plate that includes a reagent container, a sample container and a test cell where the temperatures of the containers are controlled by a heater and a Peltier cooler. For claim 6, Bell uses an arm with a probe attached to the end of the arm to remove a specific amount of reagent and sample from each container and injects the reagent and sample into a test cell (col. 3 lines 53-65; col. 4 lines 9-11 & 21-23). The arm is being interpreted as being independent of the sensor based on Figure 2a.

Therefore, it would have been obvious to one of ordinary skill in the art to employ the arm of Bell in order to load samples into the containers of Kurihara and Gaillon. The suggestion for doing so at the time would have been in order to provide sufficient mixing of the samples within the test cell (col. 4 lines 27-28).

17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bannerjee (US 6,307,630 B1) in view of Gaillon et al (WO 99/27349) (with US 6,723,554 B1 being the closest English language translation).

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18. For claim 9, Bannerjee discloses using an array (Fig. 1) of sample chambers where light from a common light source (100) is sent to each chamber by an optical fiber (101,102) where the scattered light is collected by another optical fiber and transmitted to a detector (col. 3 lines 40-45). Also, Bannerjee further discloses using a rotating arm (135) to obtain an optical sample from each sample chamber.

Furthermore, the optical data obtained from the optical fibers are sent to a conventional control electronics which converts the signal generated by the detector into a turbidity value (col. 3 lines 46-49). Moreover, the control electronics implies that this system is automatic. However, Bannerjee does not discloses using a micro-fermentor with a volume between 2 mL to 500 mL.

19. Gaillon discloses a method for measuring the optical properties of a sample by feedback control. For claim 9, Gaillon discloses using a container that has a useful volume between 10 ml and 60 ml which is used as a fermentor (col. 13 lines 2-4; col. 18 lines 16-19). Furthermore, adjusting the volume of the base device of Bannerjee with the volume of Gaillon would be within the skills of one of ordinary skill in the art based on throughput requirements for testing or the amount of sample to be fermented.

Therefore, it would have been obvious to one of ordinary skill in the art to employ the method of using a fermentor with the volume suggested by Gaillon within the device of Bannerjee in order to obtain the predictable result of fermenting and testing a sample.

20. For claim 10, Bannerjee does not specify injecting or sampling based as a function of optical property of the sample. However, Bannerjee does disclose testing the turbidity of the water coming into a sample chamber via an inlet and outlet (col. 3

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.lines 20-22; Fig. 2) where injecting is being interpreted as supplying a sample to the container. Also, since the detector of Bannerjee is used for testing water samples after filtration, it would be within the skills of one of ordinary skill in the art would send more water samples to the chambers based on the optical results. Therefore, it would be obvious to one of ordinary skill in the art to either inject or sample more water based on the optical test results of Bannerjee. The suggestion for doing so at the time would have been in order to monitor effluent from a micro-filtration plant.

Response to Arguments

21. Applicant's arguments with respect to claims 1-6 and 9-15 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection is made in view of Gaillon which discloses using a micro-bioreactor with a useful volume between 10 to 60 ml and in view of Kurihara which discloses a fluorescent detection method and apparatus that includes a Peltier element to control the temperature of the sample container.

22. Regarding Applicant's argument on page 3 of the remarks filed on 01/05/2009, that Bannerjee does not disclose a micro-fermentor with a useful volume between 2 to 500 ml, this deficiency is corrected by Gaillon. Furthermore, the control electronics of Bannerjee are being interpreted as the automatic control for the system and therefore, meets the limitation of being "automatic". Also, Applicant argues that Bannerjee does not disclose the steps of measuring, automatically, at least one optical property of a culture contained within a micro-fermentor via an external sensor, moving in robotized

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way the external sensor to another micro-fermentor, and measuring automatically at least on optical property". The Examiner disagrees with this characterization of the reference. Bannerjee measures the turbidity of a sample, which is an optical property, and the common detector is moved by a carriage screw and a stepper motor which is connected to control electronics and this movement is being interpreted as "robotized". Furthermore, "injecting" is being interpreted to mean placing a sample into the container and "sampling" is being interpreted to mean testing the sample/culture within the container. Based on this interpretation, Bannerjee meets the limitations of claim 10. Regarding Applicant's argument on page 3 paragraph 2 of the remarks filed on 01/05/2009, that an "invention can only be found obvious if there is "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (*KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)))". Bannerjee discloses the base device and method of "injecting" a sample into a container or cuvette and the step of "sampling" or testing. Further, injecting a sample into a cuvette, tube or sample container is a technique known within the art which Bannerjee discloses and Bannerjee discloses testing an optical property of the sample. Therefore, combining the two techniques to send more samples to the container would have been recognized by one of ordinary skill in the art in order to obtain the predictable result of collecting further data regarding the process such as extent of fermentation.

Conclusion

23. Claims 1-6 and 9-15 are rejected.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797